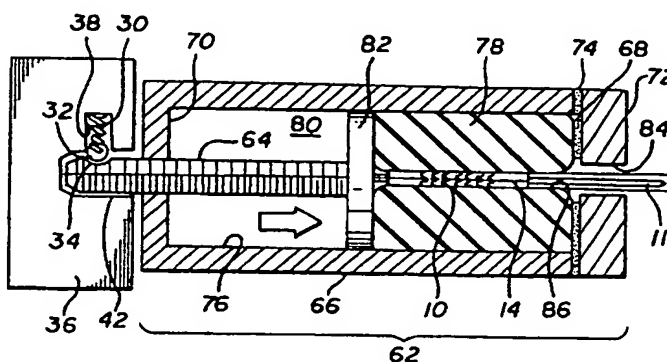




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(54) Title: METHOD AND APPARATUS FOR UNIFORMLY CRIMPING A STENT ONTO A CATHETER



(57) Abstract

A stent crimping tool (22) for firmly and uniformly crimping a stent (10) onto a balloon catheter (11) is constructed from a crimping section (24) holding the stent (10) and the balloon catheter (11) therein, wherein the crimping is actuated by a shaft (28) having an input end (40) and an output end (44), engaging the crimping section at the output end (44). The shaft (28) has a detent (34) formed into the input end (40). A gripping member (36) has an internal cavity (42) to receive the input end (40) and includes a hole proximated to the shaft (28), wherein a ball bearing (32) and a compression spring (30) are located within the hole (38) to bias the ball bearing (32) toward the shaft (28) and to engage the detent (34). When a torque is applied to the gripping member (36), it is transmitted through the ball bearing (32) to the shaft (28); if the torque exceeds a predetermined magnitude, it overcomes the force of the spring (30) on the ball bearing (32) causing the bearing to slide out of the detent (34) thereby disconnecting the applied torque from the shaft. The crimping section can be a rubber tube having a lumen holding the stent and catheter. When the shaft (28) compresses the rubber tube as it advances, the lumen collapses and crimps the stent onto the catheter. In another embodiment, the crimping section is a coiled filament suspended at both ends and having an axial space holding the stent and catheter. Rotating the shaft twists the filament which in turn constricts and crimps the stent onto the catheter.

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METHOD AND APPARATUS FOR UNIFORMLY CRIMPING
A STENT ONTO A CATHETER

BACKGROUND OF THE INVENTION

The present invention relates to an apparatus for loading a tubular graft, such as a stent, onto the distal end of a catheter assembly of the kind used, for example, in percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) procedures.

5 In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral arteries and advanced through the vasculature until the distal end of the guiding catheter is in the ostium. A guide wire and a dilatation catheter having a balloon on the distal end are introduced through the guiding catheter with the guide wire sliding within the dilatation catheter. The guide wire
10 first is advanced out of the guiding catheter into the coronary vasculature of the patient and the dilatation catheter is advanced over the previously advanced guide wire until the dilatation balloon is positioned properly across the arterial lesion. Once in position across the lesion, a flexible and expandable balloon is inflated to a predetermined size with a radiopaque liquid at relatively high pressures to radially compress the atherosclerotic plaque of the lesion
15 against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon then is deflated to a small profile so that the dilatation catheter can be withdrawn from the vasculature of the patient and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in angioplasty.

20 In angioplasty procedures of the kind referenced above, restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the development of restenosis and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a
25 stent, inside the artery at the lesion. The stent is crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter. The stent also may be of the self-expanding type.

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Because the catheter and stent travel through the vasculature of the patient, and probably through the coronary arteries, the stent must have a small delivery diameter and must be attached firmly to the catheter until the physician is ready to implant it. Thus, the stent must be loaded onto the catheter so that it does not interfere with delivery, and it must not come off the catheter until it is implanted.

In procedures where the stent is placed over the balloon portion of the catheter, it is necessary to crimp the stent onto the balloon portion to reduce its diameter and to prevent it from sliding off the catheter when the catheter is advanced through the vasculature of the patient. Non-uniform crimping can result in sharp edges being formed along the now uneven surface of the crimped stent. Further, non-uniform stent crimping may not achieve the desired minimal profile for the stent and catheter assembly. Where the stent is not reliably crimped onto the catheter, the stent may slide off the catheter and into the patient's vasculature prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Therefore, it is important to insure the proper crimping of a stent onto a catheter in a uniform and reliable manner.

This crimping is often done by hand, which can be unsatisfactory due to the uneven application of force resulting in non-uniform crimps. In addition, it is difficult to visually judge when a uniform and reliable crimp has been applied.

Some self-expanding stents are difficult to load by hand onto a delivery device such as a catheter. Further, the more the stent is handled the higher the likelihood of human error, which is antithetical to a properly crimped stent. Accordingly, there is a need in the art for a device for reliably crimping a stent onto a catheter.

There have been attempts at devising a tool for crimping a stent onto a balloon delivery catheter. An example of such a tool comprises a series of plates having substantially flat and parallel surfaces that move in a rectilinear fashion with respect to each other. A stent carrying catheter is disposed between these surfaces, which surfaces crimp the stent onto the outside of the catheter by their relative motion and applied pressure. The plates have multiple degrees of freedom and may have force-indicating transducers to measure and indicate the force applied to the catheter during crimping of the stent.

Another stent loading tool design is comprised of a tubular member housing a bladder. The tubular member and bladder are constructed to hold a stent that is to be crimped onto a balloon catheter assembly. Upon placement of the stent over the balloon portion of the

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catheter, a valve in the loading tool is activated to inflate the bladder. The bladder compresses the stent radially inward to a reduced diameter onto the balloon portion of the catheter to achieve a snug fit. In this way, the stent is crimped onto the distal end of a balloon catheter with a minimum of human handling. The foregoing stent crimping tools are disclosed in, for example, U.S. Patent Nos. 5,437,083 and 5,546,646 to Williams et al.

Yet another stent crimping tool is known in the art as the BARD XT, which is actually a stent loader. It is constructed from a rigid, tubular body with a ball at one end connected to a plurality of long, thin strips passing through the tubular body. An uncrimped stent is placed over the plurality of long, thin strips, which hold the stent in an expanded state. The balloon portion of a catheter is inserted into the cylindrical space formed by the plurality of strips. When the user pulls the ball while holding the tubular body against the stent, the strips are slid from beneath the stent and the stent is transferred onto the balloon portion.

Still another conventional stent crimping tool is manufactured by Johnson & Johnson and appears similar to a hinged nutcracker. Specifically, the tool is comprised of two hand operated levers hinged at one end and gripped in the palm of the hand at the opposite end. A cylindrical opening holding a crimping tube is provided through the mid-portion of the tool to receive therein a stent loaded onto a balloon catheter. The crimping operation is performed by the user squeezing the handle thereby pressing the crimping tube which in turn pinches the stent onto the balloon catheter.

While the prior art devices are suitable for crimping stents onto balloon catheters, they suffer from problems such as non-uniform crimping forces, resulting in non-uniform crimps. Consequently, they are unsuitable for use by physicians in a catheterization laboratory who desire to crimp the stent onto the balloon catheter.

SUMMARY OF THE INVENTION

Both PTCA and PTA procedures have become commonplace in treating stenoses or lesions in blood vessels and coronary arteries. In approximately 35% to 40% of the procedures, restenosis may develop requiring a further angioplasty, atherectomy or bypass procedure to return the patency of the vessel. Intravascular stents are now being deployed after PTCA and PTA procedures, and after atherectomies, in order to help prevent the development of restenosis. Importantly, such stents, mounted on the balloon portion of a

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catheter, must be tightly crimped to provide a low profile delivery diameter, and to ensure that the stent stays on the balloon until the balloon is expanded and the stent is implanted in the vessel. The present invention is directed to a crimping tool that can repeatedly provide a uniform and tight crimp to ensure the low profile diameter of the stent on the balloon portion of the catheter, and to ensure that the stent remains firmly attached until it is implanted in the vessel by expanding the balloon.

The present invention is directed to a method and apparatus to obtain consistent crimping of a stent on a balloon catheter independent of the balloon profile. This is accomplished by limiting the amount of force that is applied to crimp the stent by using a clutch that disconnects the applied torque at a predetermined level.

In particular, the present invention is directed to a tool for crimping a stent onto a balloon catheter, comprising a crimping section holding the stent and the balloon catheter therein; a shaft having an input end and an output end, engaging the crimping section at the output end, which shaft when rotated actuates the crimping section to crimp the stent; a detent formed into the input end of the shaft; a gripping member having an internal cavity to receive the input end of the shaft, wherein the cavity includes a hole proximate to the shaft; a stop member; a biasing member disposed in the hole and biasing the stop member into engagement with the detent; whereby applying a torque to the gripping member beyond a predetermined level overcomes the force of the biasing member and slides the stop member out of the detent to disengage the applied torque from the shaft.

Rotation of the shaft halts, and the magnitude of the crimping force encountered by the stent levels off or drops off due to resilience or backlash in the system. Damage to the stent from excessive crimping force is avoided.

In one exemplary embodiment, the crimping section comprises a housing having an internal chamber with an enclosed first end, and an open second end having threads, wherein the output end of the shaft is partially disposed within the internal chamber through the open second end of the housing, and wherein the input end of the shaft includes threads that engage the threads of the internal chamber; and an elastic tubing having a lumen, wherein the tubing is disposed within the internal chamber adjacent the enclosed first end, and the output end of the shaft is disposed adjacent the tubing. Accordingly, the stent and balloon catheter are positioned within the lumen and rotation of the shaft advances the shaft into the tubing, compressing the tubing, and crimping the stent.

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In another exemplary embodiment, the crimping section comprises a rigid chassis having a hollow interior enclosed by a closed back end and leading to an open front end, wherein the back end includes a threaded opening; an end cap enclosing the open front end, the end cap including a central opening; an elastic tube disposed within the hollow interior
5 adjacent to the front end and having a length less than a length of the hollow interior to define a chamber adjacent to the back end; a piston slidably disposed within the chamber; wherein the shaft passes through the closed back end of the chassis and the shaft includes threads engaging the threads of the back end, and the output end of the shaft engages the piston so that the shaft when rotated displaces the piston to compress the elastic tube; whereby the stent
10 is loaded onto the catheter and is inserted through the central opening into the elastic tube, and the compressed elastic tube squeezes the stent radially onto the catheter.

In yet another exemplary embodiment, the crimping section comprises a base having at least first and second spaced apart supports, wherein the shaft is rotatably disposed on the second support with the output end of the shaft extending toward the first support; a coiled
15 filament having an axial space and being attached to the first support and the output end of the shaft and extending between the first and second supports; whereby inserting the stent and catheter into the axial space of the coiled filament and rotating the shaft reduces the diameter of the axial space thereby crimping the stent onto the catheter.

In conclusion, it is clear that the present invention tool can be adapted to a variety of
20 stent crimping sections that are operated by application of torque. The clutch of the present invention ensures that the amount of force applied during the crimping process is controlled. This is achieved by disconnecting the gripping member from the shaft at a predetermined level of torque. Doing so disrupts the transfer of torque to the crimping section of the tool, which in turn levels the amount of crimping force exerted on the stent.

25 With precise control of applied crimping forces, the present invention tool is capable of homogeneously crimping a stent onto a balloon catheter. Such a crimping tool is highly useful to cardiologists, for example. Such physicians are often concerned with proper deployment of the stent within the patient that it is desirable to have a consistently and reliably crimped stent. The present invention tool is further a time saver, because the stent
30 crimping procedure can be performed fairly efficiently and quickly. These and other advantages of the present invention will become apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view, partially in section, depicting a stent that has been crimped onto a delivery catheter and disposed within a vessel.

FIG. 2 is a sectional view of a preferred embodiment of the invention, showing the clutch mechanism and the crimping section of the tool.

FIG. 3 is a cross-sectional view of an alternative embodiment of the invention tool shown in FIG. 2.

FIG. 4 is a perspective view of an embodiment of the crimping tool according to the invention wherein the crimping section includes a coiled filament used to crimp the stent.

FIGS. 5 and 6 are simplified schematic diagrams depicting a stent crimping operation performed by the embodiment shown in FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGURE 1 illustrates an intravascular stent 10 which is mounted onto a delivery catheter 11. The stent 10 generally comprises a plurality of radially expandable cylindrical elements 12 disposed coaxially and interconnected by members 13 disposed between adjacent cylindrical elements 12. The delivery catheter 11 has an expandable portion or balloon 14 for expanding the stent 10 within a coronary artery 15 or other vessel such as saphenous veins, carotid arteries, arteries, and veins. An artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted essentially is the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyvinyl chloride, polyethylene terephthalate and other like polymers. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon 14.

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An optional retractable protective delivery sleeve 20 may be provided to further insure that the stent 10 stays in place on the balloon 14 of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion of the balloon 14.

In order to implant the stent 10, it first is mounted onto the inflation balloon 14 on the distal extremity of the delivery catheter 11. The stent 10 is crimped down onto the balloon 14 to insure a low profile. Embodiments of the present invention are directed to this crimping procedure.

The catheter-stent assembly can be introduced into the patient's vasculature through processes known in the art. Briefly, a guide wire 18 is disposed across the arterial section where an angioplasty or atherectomy has been performed requiring a follow-up stenting procedure. In some cases, the arterial wall lining may be detached so that the guide wire 18 is advanced past the detached or dissected lining 16 and the catheter-stent assembly is advanced over the guide wire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. Prior to inflation of the balloon 14, an optional delivery sleeve 20 is retracted to expose the stent 10. Depending on the balloon-and-stent assembly, a delivery sleeve may be unnecessary. The balloon 14 of the delivery catheter 11 then is inflated using an inflation fluid. Expansion of the balloon 14 in turn expands the stent 10 against the artery 15. Next, the balloon 14 is deflated and the catheter 11 is withdrawn, leaving the stent 10 to support the damaged arterial section. As mentioned above, in order to insure proper seating of the stent 10 onto the balloon 14, and to insure proper deployment of the stent 10 at the site of the damage within the artery 15, the stent crimping procedure is important.

FIG. 2 is a cross-sectional view of a preferred embodiment of a stent crimping tool 22 according to the present invention. The stent crimping tool 22 as shown preferably has a crimping section 24 and an actuation section 26. The actuation section 26 is rotated and torque is transmitted through a shaft 28 to the crimping section 24.

In order to limit the amount of torque transmitted to the shaft 28 and thus to limit the amount of crimping force, embodiments of the present invention include a clutch mechanism. In the preferred embodiment, the clutch mechanism includes a compression spring 30, a ball bearing 32, and a detent 34 located on the shaft 28. As the gripping member 36 (which can

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be a knob, a crank, a knurled spindle, or the like) is rotated, torque is transmitted through a stop member (here the ball bearing 32) to the detent 34. The spring 30, which is positioned within a hole 38, biases the ball bearing 32 into the detent 34 with sufficient force to maintain the transfer of torque from the gripping member 36 to the shaft 28. If, however, a
5 predetermined amount of torque is exceeded, the axial force of the compression spring 30 is overcome, causing the ball bearing 32 to slide out of the detent 34 and to retract into the hole 38. Of course, this predetermined amount of torque can be adjusted by modifying the spring force, the depth of the detent, the size of the ball bearing, and other parameters known in the art.

10 At that instant, the linkage between the gripping member 36 and the shaft 28 is broken because the ball bearing 32 is free to rotate and slide along the outer circumference of the shaft 28. The clutch mechanism thus limits the torque that is delivered through the shaft 28 into the crimping section 24.

15 In the exemplary embodiment shown in FIG. 2, the detent 34 is a semi-spherical cut-out formed on the input end 40 of the shaft 28. The input end 40 also is received within the cavity 42 of the gripping member 36. The gripping member 36 may be formed in a cylindrical shape for easy gripping as shown, or may take other grippable shapes known in the art. Further, a resilient piece of material may be used to replace the spring 30 to bias the ball bearing into the shaft 28. For example, a sponge-like material can be used that has
20 compliance and the level of resilience needed to urge the ball bearing 32 into the detent 34 in order to transfer torque between the gripping member 36 and the shaft 28.

At the opposite end of the shaft 28 is an output end 44, which preferably is located adjacent resilient tubing 46. The shaft 28 further includes external threads 48, which are meant to engage internal threads 50 formed inside a housing 52 of the crimping section 24.
25 The resilient tubing 46 fits within a hollow interior 54 of the housing 52, wherein the latter is sufficiently rigid to not expand or distort under pressure. At the opposite end of the housing 52 is an end cap 56 that encloses the back end.

Thus, as the user manually rotates the shaft 28, through application of torque to the gripping member 36, the shaft 28 advances into and compresses the resilient tubing 46.
30 Within the resilient tubing 46 is a lumen 58 containing the uncrimped stent 10 already loaded onto the balloon 14 of the catheter 11. An end cap 56 has an optional central opening 60 in communication with the lumen 58. Hence, the delivery catheter 11 can be inserted through

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the central opening 60 and advanced into alignment with the uncrimped stent 10 inside the lumen 58. As compression of the resilient tubing 46 takes place, the length of the resilient tubing 46 is shortened, thereby causing the lumen 58 to collapse and simultaneously to crimp the stent 10 onto the delivery catheter 11. After the crimping step, the shaft 28 is rotated in the opposite direction to retract it away from the resilient tubing 46, which regains its original shape. Thereafter, the crimped stent and catheter assembly can be withdrawn through the central opening 60.

In an alternative embodiment, a through-hole (not shown) can be formed through the length of the shaft 28 and through the gripping member 36. After the crimping step, the crimped stent and the catheter assembly can be advanced over a guide wire (not shown), passing through the through-hole, and out the opposite end of the tool. Therefore, in this alternative embodiment, the crimped stent and the catheter assembly immediately can be advanced over the guide wire to the patient for implantation after the crimping step.

During the crimping step, if maximum torque is exceeded, as explained above, the ball bearing 32 slides out of the detent 34. On the other hand, if the gripping member 36 is rotated continuously, the ball bearing 32 can be reseated within the detent 34 during a subsequent revolution of the gripping member 36 about the input end 40, thereby re-engaging the linkage between the shaft 28 and the gripping member 36. At that moment, torque can be reapplied by rotating the gripping member 36 in either direction to advance or to retract the shaft 28. By alternately advancing and retracting the shaft 28, it is possible to repeat the crimping step and to insure a firm and consistent crimp of the stent 10 onto the catheter 11. To be sure, it also is possible to rotate the delivery catheter 11 during each cycle of the crimping step.

FIG. 3 is an alternative embodiment of the exemplary embodiment shown in FIG. 2. More precisely, FIG. 3 is a cross-sectional view showing a crimping section 62 that is a modification of the crimping section 24 from FIG. 2. As seen in FIG. 3, torque is transferred between the gripping member 36 and the crimping section 62 through a threaded shaft 64. This crimping section 62 is similar to that disclosed in co-pending U.S. Serial No. 09/063,905 for an Inflator-Driven Rubber-Compression Crimping Tool," filed April 21, 1998.

In the embodiment of FIG. 3, the crimping section 62 is constructed from a cylindrically-shaped chassis 66 having an open end 68 and a closed end 70. The open end 68 is sealed closed with an optional end cap 72 that is bonded to the open end 68 using an

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adhesive 74 of a type known in the art. Alternatively, the optional end cap 72 may be attached to the chassis 66 using threads, snaps, clamps, or other mechanical means known in the art.

Within the cylindrically-shaped chassis 66 is a hollow interior 76 that contains an elastic tube 78 that is coaxially disposed within the chassis 66. Notably, the elastic tube 78 has a length that is shorter than the length of the hollow interior 76. Because of this difference in length, and because the elastic tube 78 is disposed adjacent the open end 68, a chamber 80 is formed adjacent to the closed end 70. Slidably disposed within the chamber 80 is a movable piston 82. The shaft 64 engages the piston 82 as shown in FIG. 3.

The end cap 72 includes a central opening 84 that is aligned and in communication with an axial space 86 of the elastic tube 78. The central opening 84 allows the stent-catheter assembly to be inserted into the crimping section 62 prior to undergoing the crimping procedure.

Leading up to the procedure, a user introduces the stent 10 already loaded onto the balloon portion 14 of the catheter 11 into the axial space 86 within the elastic tube 78. In the illustrated embodiment, the inside diameter of the elastic tube 78 is slightly greater than the outside diameter of the uncrimped stent 10, or of the uncrimped stent 10 and the balloon 14, respectively.

As the gripping member 36 is rotated, torque is transmitted through the spring 30 to the ball bearing 32 and to the walls of the detent 34 formed in the shaft 64. The shaft 64 once in rotation advances the piston 82 into the elastic tube 78 as indicated by the arrow. As a result, the elastic tube 78 is compressed axially or lengthwise. The elastic material of the elastic tube 78 must maintain a constant volume due to its surface elasticity and containment within the confines of the hollow interior 76. Continuous compression of the elastic tube 78 by the piston 82 causes the material of the elastic tube 78 to displace axially and then radially into the axial space 86, in effect collapsing that space. This decreases the diameter of the axial space 86. In turn, the stent 10 contained inside the axial space 86 is compressed radially onto the balloon portion 14 of the catheter 11.

As in the previously described embodiment, exceeding a pre-determined torque on the gripping member 36 disengages the ball bearing 32 from the detent 34 to disconnect the application of torque to the shaft 64. On the other hand, insofar as the gripping member 36 and the shaft 64 are linked through the clutch mechanism, it is possible to rotate and counter-

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rotate the shaft 64 to advance and retract, respectively, the piston 82. Indeed, it is possible to cycle through the crimping step over and over as necessary.

In the various exemplary embodiments of the present invention crimping tool shown in FIGS. 2 and 3, the housing pieces, piston, shafts, gripping member, etc. can be made from a rigid, injection molded plastic material. Also, translucent and transparent materials can be used so that the task at hand can be monitored visually. Embodiments of the crimping tool according to the present invention have a design that is well suited for fabrication from surgical steel as well. The resilient tubing 46 and the elastic tube 78 of each embodiment can be made from rubber or other elastomers known in the art.

FIG. 4 is a perspective view of an alternative embodiment of a crimping tool according to the present invention. In this embodiment, a stent crimping section 90 contains a filament used to constrict a stent onto a balloon catheter inserted within an axial space formed by the coiled filament. Torque still is applied through the gripping member 36, which is connected to a shaft 92. As best seen in this figure, the surface of the gripping member 36 optionally may be contoured or knurled by a pattern 94 to provide a better gripping surface.

The stent crimping section 90 is similar to that disclosed in co-pending U.S. Serial No. 08/962,632 for a "Stent Crimping Tool and Method of Use," filed November 3, 1997. In FIG. 4, the stent crimping section 90 includes a base 96, a first vertical support 98, and a second vertical support 100, wherein the two vertical supports 98 and 100 are spaced apart on the base 96. The shaft 92 rotatably passes through an opening in the second vertical support 100. A cam 102 is affixed on the shaft 92 whereby the cam rotates with the shaft 92.

The cam 102 optionally includes an obstruction which, in the preferred embodiment, comprises teeth 104 located at the circumference of the cam 102 and are designed to engage a pawl 106. The pawl 106 is positioned on the base 96 and biased into the teeth 104. Together, the cam 102, the teeth 104, and the pawl 106 form a ratchet mechanism that permits rotation in one direction yet prevents rotation of the shaft 92 in the opposite direction.

Attached to the output end 108 of the shaft 92 is one end of a coiled filament 110. The opposite end of the coiled filament 110 is connected to a first vertical support 98. In the preferred embodiment shown in FIG. 4, the coiled filament 110 is a coiled tension spring with its ends hooked to pins 112 and 114.

In FIG. 4, the crimping tool has fairly high extending vertical supports 98, 100, such that the shaft 92 passes through the second vertical support 100 rather than just resting upon

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it. An optional bearing 116 is located inside the second vertical support 100 to minimize rotational friction between the shaft 92 and the second vertical support 100.

Also, a through-hole 118 is provided in the first vertical support 98 and is in communication with an axial space 120 that is defined by the collection of coils of the coiled filament 110. When the tool is used, the through-hole 118 allows the stent-catheter assembly to be passed therethrough into the axial space 120.

FIGS. 5 and 6 are simplified schematic diagrams of the preferred embodiment of the present invention shown in FIG. 4, to illustrate the crimping operation. Specifically, FIG. 5 provides a side elevational view of the embodiment whereby the stent 10 and the balloon 14 have been inserted into the axial space 120. An optional sheath 122 is shown covering the stent-catheter assembly. Inside the gripping member 36, the ball bearing 32 has been biased by the compression spring 30 into the detent 34. The gripping member 36 can be rotated to apply torque through the shaft 92, thereby twisting the coiled filament 110 in order to constrict the stent-catheter assembly inside the axial space 120.

FIG. 6 shows completion of the crimping step after the coiled filament 110 has been twisted. Also shown in FIG. 6 is the instant when maximum torque has been exceeded so that the ball bearing 32 has slid out of the detent 34 and is riding on the outside diameter of the shaft 92. At this very instant, the applied torque from the gripping member 36 is disconnected from the shaft 92 and from the constricted coiled filament 110. The natural resiliency of the coiled filament 110 at this moment tends to counter-rotate the shaft 92. However, the pawl 106 biased by the spring 124 engages the cam 102 to prevent the counter-rotation. Of course, disengagement of the pawl 106 from the cam 102 would permit free rotation of the shaft 92 in either direction. At the input end 126 of the shaft 92, the shaft 92 rotates independently of the gripping member 36 until the ball bearing 32 again is seated within the detent 34 during one of the revolutions of the shaft 92 relative to the gripping member 36. Upon re-engagement, the gripping member 36 again is linked to the shaft 92 to control its rotation. In the preferred embodiment of FIG. 4, parts forming the crimping section 90 are made from nylon or from a comparable polymer known in the art. The coiled filament 110, for example, can be a metal tension spring, a resilient polymer ribbon made from a material manufactured under the name MYLAR by the E.I. duPont deNemours Company, that is formed into a coil. The coiled filament can have a flat, polygonal, or round cross-sectional shape.

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5 The embodiments of the present invention preferably are sterilized and intended to be used in a catheterization laboratory by a trained technician or cardiologist. As will be appreciated by those skilled in the art, a crimping tool according to the present invention is designed both for single use applications in a catheterization laboratory by a physician, or for multiple use applications in a sterile environment in a high volume manufacturing facility. In such a manufacturing facility where sterile conditions exist, a crimping tool according to the present invention can be used repeatedly to crimp stents onto balloons until the mechanism wears out. Thus, repeated uses of the present invention are contemplated for controlled, sterile environments, as are single use applications when operated by catheterization laboratory personnel.

10 Further, embodiments of a crimping tool according to the present invention can be used with any stent that is released without a delivery system. The crimping tool also may be sold alone, because its design is robust enough to undergo many uses.

15 Other modifications can be made to the present invention without departing from the scope thereof. The specific dimensions, procedural steps, and materials of construction are provided as examples, and substitutes readily are contemplated which do not depart from the invention.

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WHAT IS CLAIMED IS:

1. A tool for crimping a stent onto a balloon catheter, comprising:
a crimping section holding the stent and the balloon catheter therein;
a shaft having an input end and an output end, engaging the crimping section at the
output end, which shaft when rotated actuates the crimping section to crimp the stent;
5 a detent formed into the input end of the shaft;
a gripping member having an internal cavity to receive the input end of the shaft,
wherein the cavity includes a hole proximate to the shaft;
a stop member; and
a biasing member disposed in the hole and biasing the stop member into engagement
10 with the detent.

2. The stent crimping tool according to claim 1, wherein the crimping section
further comprises:

a housing having an internal chamber with an enclosed first end, and an open second
end having threads;

5 wherein the output end of the shaft is partially disposed within the internal chamber
through the open second end of the housing, and wherein the input end of the shaft includes
threads that engage the threads of the internal chamber;

an elastic tubing having a lumen, wherein the tubing is disposed within the internal
chamber adjacent the enclosed first end, and the output end of the shaft is disposed adjacent
10 the tubing;

whereby the stent and balloon catheter are positioned within the lumen and rotation of
the shaft advances the shaft into the tubing thereby crimping the stent onto the catheter.

3. The stent crimping tool according to claim 2, wherein the biasing member
includes a compression spring.

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4. The stent crimping tool according to claim 2, wherein stop member includes a ball bearing.

5. The stent crimping tool according to claim 2, wherein detent includes a semi-spherical cutout.

6. The stent crimping tool according to claim 2, wherein the elastic tubing includes a rubber material.

7. The stent crimping tool according to claim 2, wherein the first end of the housing includes an opening in communication with the lumen.

8. The crimping tool according to claim 1, wherein the crimping section further comprises:

a rigid chassis having a hollow interior enclosed by a closed back end and leading to an open front end, wherein the back end includes a threaded opening;

5 an end cap enclosing the open front end, the end cap including a central opening;

an elastic tube disposed within the hollow interior adjacent to the front end and having a length less than a length of the hollow interior to define a chamber adjacent to the back end;

a piston slidably disposed within the chamber;

10 wherein the shaft passes through the closed back end of the chassis and the shaft includes threads engaging the threads of the back end, and the output end of the shaft engages the piston so that the shaft when rotated displaces the piston to compress the elastic tube;

whereby the stent is loaded onto the catheter and is inserted through the central opening into the elastic tube, and the compressed elastic tube squeezes the stent radially onto the catheter.

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9. The stent crimping tool according to claim 8, wherein the end cap is mechanically attached to the open front end.

10. The stent crimping tool according to claim 8, wherein the end cap is bonded to the open front end.

11. The stent crimping tool according to claim 1, wherein the crimping section further comprises:

a base having at least first and second spaced apart supports;

wherein the shaft is rotatably disposed on the second support with the output end of the shaft extending toward the first support;

a coiled filament having an axial space and being attached to the first support and the output end of the shaft and extending between the first and second supports;

whereby inserting the stent and catheter into the axial space of the coiled filament and rotating the shaft reduces the diameter of the axial space thereby crimping the stent onto the catheter.

12. The stent crimping tool according to claim 11, wherein the coiled filament includes a coiled spring.

13. The stent crimping tool according to claim 11, wherein the coiled filament includes a flat cross-sectional shape.

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14. The stent crimping tool according to claim 11, wherein the crimping tool further comprises:

a cam affixed to the shaft and having an obstruction at a circumference thereof; and
a pawl disposed on the base and biased into engagement with the cam obstruction to prevent free rotation of the shaft.

15. The stent crimping tool according to claim 11, wherein the tool further includes a sheath at least partially covering the stent and catheter.

16. A method for crimping a stent onto a balloon catheter, comprising the steps of:
providing a crimping section;
loading the stent onto the balloon catheter;
inserting the stent and the balloon catheter therein into the crimping section;
providing a shaft having an input end and an output end so that the shaft engages the crimping section at the output end, which shaft when rotated actuates the crimping section to crimp the stent;
providing a detent formed into the input end of the shaft;
providing a gripping member having an internal cavity to receive the input end of the shaft, wherein the cavity includes a hole proximate to the shaft;
providing a stop member;
providing a biasing member disposed in the hole;
biasing the stop member into engagement with the detent; and
applying a torque to the gripping member to crimp the stent;
wherein if the torque exceeds the force of the biasing member on the stop member, the stop member slides out of the detent.

17. The method of claim 16, wherein the method further comprises the steps of:
decreasing an amount of applied torque;
aligning the stop member within the detent; and
increasing the amount of applied torque.

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18. The method of claim 16, wherein the stop member includes a ball bearing.

19. The method of claim 16, wherein the step of providing a crimping section further comprises the steps of:

providing a housing having an internal chamber with an enclosed first end, and an open second end having threads;

5 locating at least partially the output end of the shaft within the internal chamber through the open second end of the housing;

providing threads on the input end of the shaft that engage the threads of the internal chamber;

10 providing an elastic tubing having a lumen within the internal chamber adjacent the enclosed first end, and the output end of the shaft is disposed adjacent the tubing;

inserting the stent and balloon catheter within the lumen;

whereby applying torque to the gripping member advances the shaft into and compressing the tubing thereby crimping the stent.

20. The method of claim 16, wherein the step of providing a crimping section further comprises the steps of:

providing a base having at least first and second spaced apart supports;

5 rotatably disposing the shaft on the second support with the output end of the shaft extending toward the first support;

providing a coiled filament having an axial space and being attached to the first support and the output end of the shaft and extending between the first and second supports;

inserting the stent and catheter into the axial space of the coiled filament;

10 whereby rotating the gripping member to turn the shaft reduces the diameter of the axial space thereby crimping the stent onto the catheter.

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FIG. 1

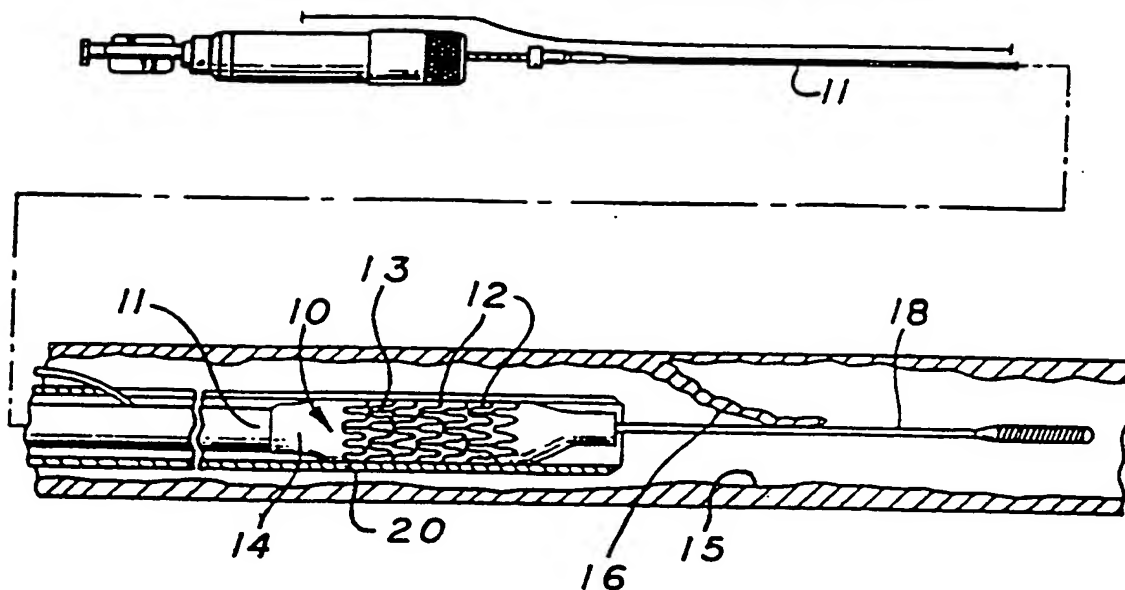
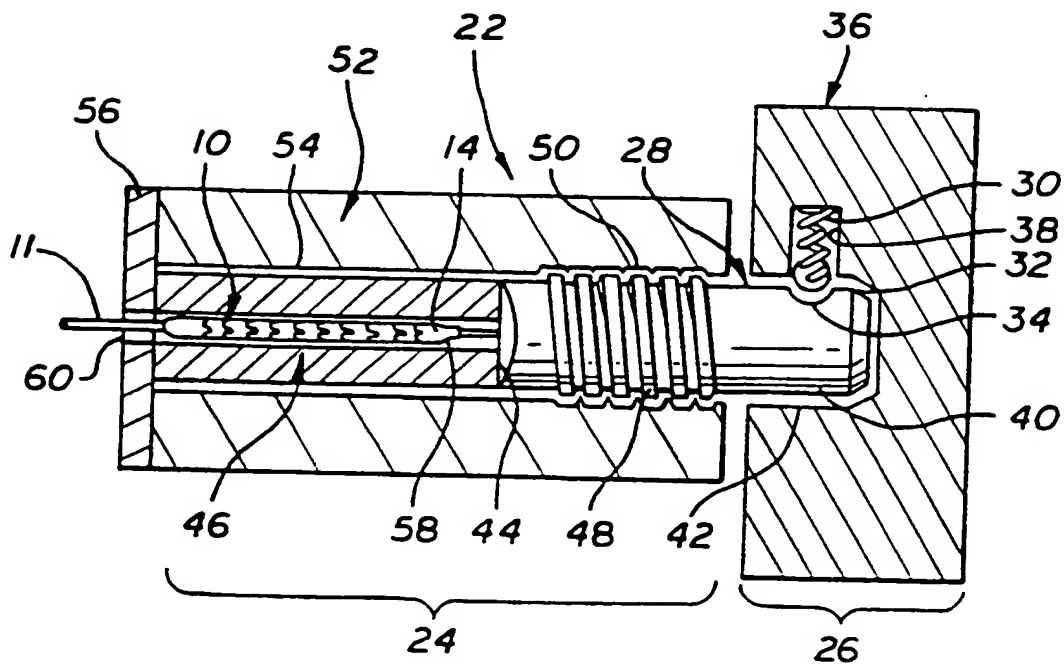


FIG. 2



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FIG. 3

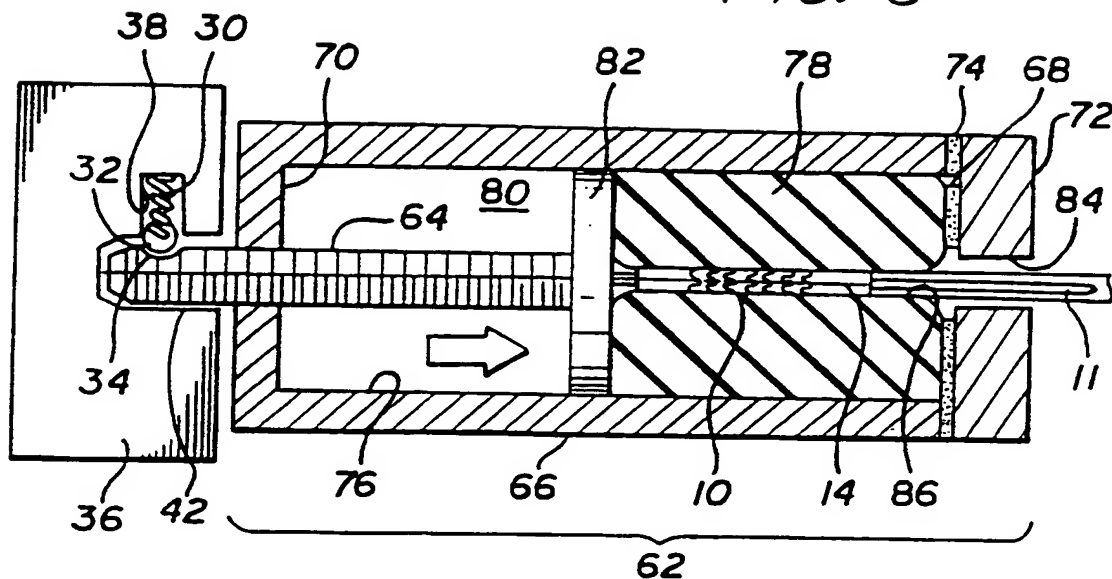
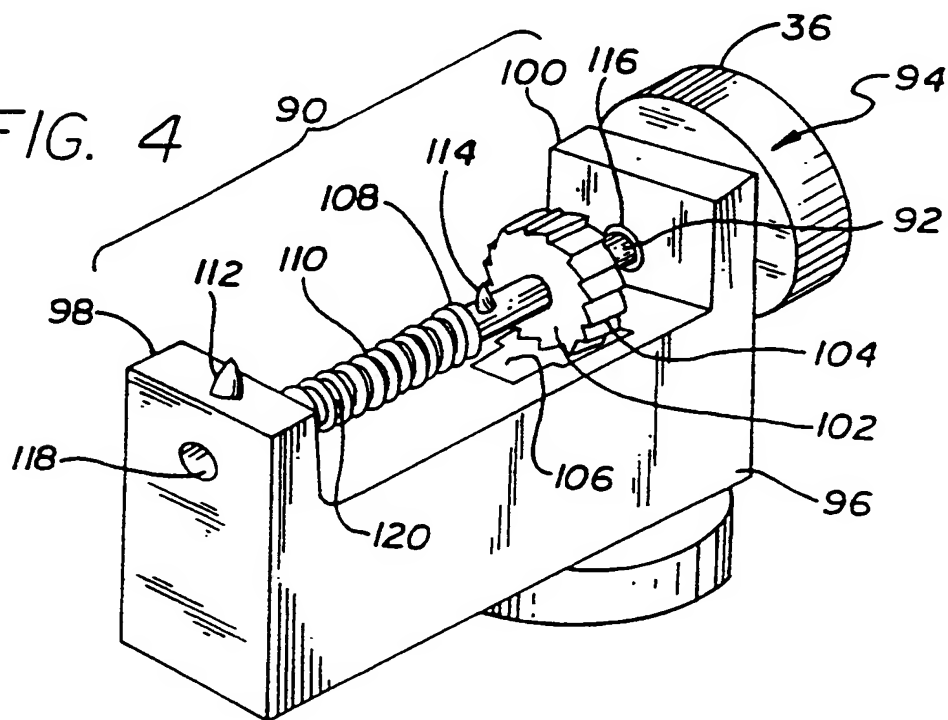


FIG. 4



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FIG. 5

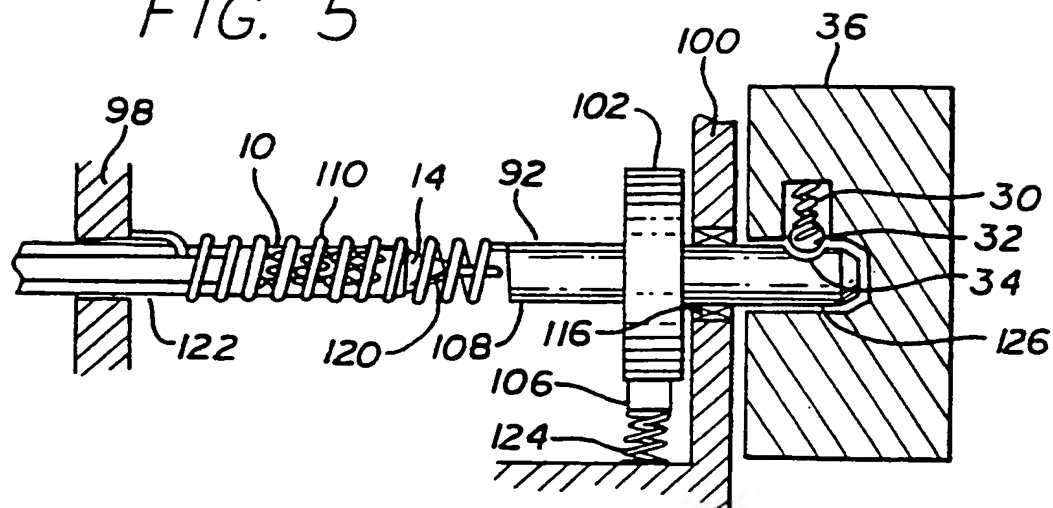
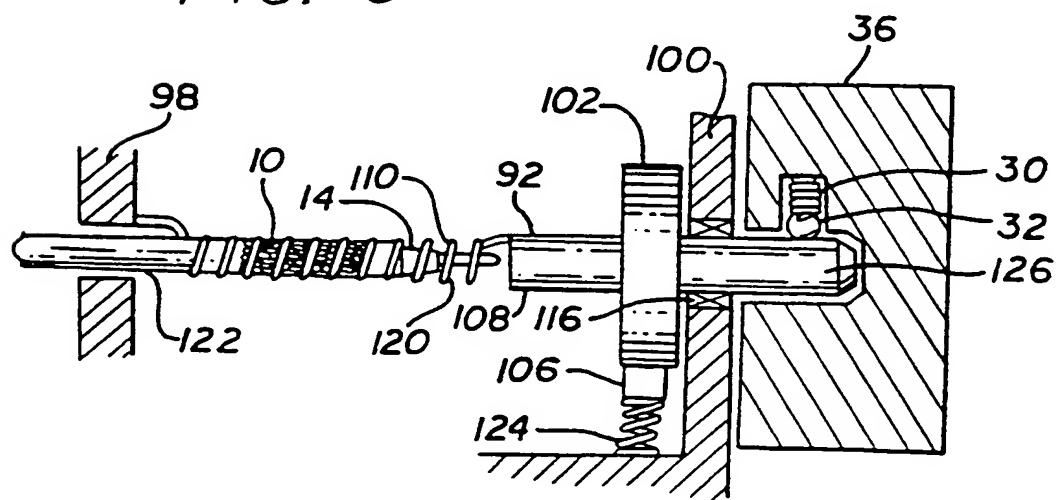


FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/09632

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F F16D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 826 346 A (CORDIS CORP) 4 March 1998 (1998-03-04) column 9, line 39 - column 10, line 17; figures column 11, line 36 - line 46 ----	1,16
A	US 5 626 604 A (COTTONE JR ROBERT J) 6 May 1997 (1997-05-06) column 9, line 47 - column 10, line 14; figures ----	1,16,19
A	US 4 864 924 A (STORACE ANTHONY) 12 September 1989 (1989-09-12) ----	
A	US 4 373 923 A (KILWIN THOMAS C) 15 February 1983 (1983-02-15) -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
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Date of the actual completion of the international search

30 July 1999

Date of mailing of the international search report

18/08/1999

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INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 99/09632

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0826346	A	04-03-1998	US 5836952 A	17-11-1998
			CA 2211694 A	21-02-1998
US 5626604	A	06-05-1997	CA 2191370 A	06-06-1997
			EP 0778009 A	11-06-1997
US 4864924	A	12-09-1989	AU 2563188 A	29-06-1989
			CA 1321323 A	17-08-1993
			CH 679958 A	15-05-1992
			DE 3841251 A	06-07-1989
			FR 2624796 A	23-06-1989
			GB 2213773 A, B	23-08-1989
US 4373923	A	15-02-1983	JP 56127827 A	06-10-1981
			US 4746320 A	24-05-1988

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